

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference P-6259-PC		Date of mailing (day/month/year) 02 AUG 2004
FOR FURTHER ACTION See paragraph 2 below		
International application No PCT/IL04/01182	International filing date (day/month/year) 29 December 2004 (29.12.2004)	Priority date (day/month/year) 31 December 2003 (31.12.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 1/04, 1/06 and US Cl.: 600/117, 476		
Applicant GIVEN IMAGING LTD		

1 This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|-------------|--|
| <input checked="" type="checkbox"/> | Box No I | Basis of the opinion |
| <input type="checkbox"/> | Box No II | Priority |
| <input type="checkbox"/> | Box No III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No V | Reasoned statement under Rule 43bis 1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No VI | Certain documents cited |
| <input type="checkbox"/> | Box No VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No VIII | Certain observations on the international application |

2 FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66 1bis(b) that written opinions of this International Searching Authority will not be so considered

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220

3 For further details, see notes to Form PCT/ISA/220

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer John P. Leubecker Telephone No (571) 272-2975
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IL04/01182

Box No. I Basis of this opinion

1 With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item

- ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b))

2 With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b format of material

- ☐ in written format
☐ in computer readable form

c time of filing/furnishing

- ☐ contained in international application as filed
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search

3 ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished

4 Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Statement

Novelty (N)	Claims <u>13</u>	YES
	Claims <u>1-12, 14-28</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-28</u>	NO
Industrial applicability (IA)	Claims <u>1-28</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-28 meet the criteria set forth in PCT Article 33(4) because the claimed subject matter can be made and/or used in industry

**WRITTEN OPINION OF THE
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claim 6 is objected to under PCT Rule 66 2(a)(v) as lacking clarity under PCT Article 6 because claim 6 is indefinite for the following reason(s): the location of the detector has nothing to do with whether or not illumination from the illumination source is received a the imager It appears that this claim should be more properly reciting the location of the illumination source, not the detector

**WRITTEN OPINION OF THE
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International application No
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Supplemental Box

In case the space in any of the preceding boxes is not sufficient

V. 2. Citations and Explanations:

Claims 1-6, 8-12, 14-16, 18-26 and 28 lack novelty under PCT Article 33(2) as being anticipated by Kawashima. Kawashima discloses an in-vivo device (endoscope 1) comprising an illumination source (10a), a detector (9a), and a processor (14a,16), which, based on signals from the detector, determines a location (col 3, lines 48-53). The detectors receive light from the body lumen wall (Fig 5). The processor indicates movement by determining relative distances to the lumen walls, whether it is one area to another or from a small lumen to a large one. The device includes an imager (objective lens system 6). Illumination from source (10a) is not received by imager (6) (note that illumination source (10a) is on lateral side of the device whereas the imager is facing distally). The device further includes a primary light source (8) positioned behind an optical window (4). The imager can be considered a detector since objective lens system (6) detects light for imaging. The processor (as shown in Figure 4) is disposed within the device (col 4, lines 8-12). The processor receives signals from the detector and controls movement of the device and is thus a "controller". The device further comprises a transmitter (wire 12a). As to the method claims, the intensity of light (which is a quality of light) is compared and the result (predetermined threshold) indicates the location within the lumen. The result controls a mode of bending in the operation unit.

Claims 1-5, 7-12, 14, 16-18, 20-24 and 26-28 lack novelty under PCT Article 33(2) as being anticipated by Avni et al. Avni et al. disclose swallable capsule comprising an illumination source (38N), a detector (32), a processor/controller (36, Fig 2) disposed within the device or, an optical window (21) and a transmitter (34). The detector is an imager (CMOS or CCD, [0034]) that is configured to receive light and indicate movement (plurality of frames). The controller/processor (36) is configured to receive signals from the detector [0037] and trigger an event (change mode) in the device (e.g., transmit image data, [0038]). Using another detector (42 or 67), the location (whether or not the capsule is close to the lumen wall) can be determined ([0055]) and an event (illumination intensity) can be controlled.

Claim 7 lacks an inventive step under PCT Article 33(3) as being obvious over Kawashima. Kawashima discloses that the detector is a "light receiving element adapted to produce an electromotive force in response to reflected light" but fails to disclose any particular kind. It would have been obvious to one of ordinary skill in the art to use any known light receiving element at the time of the invention. All of CMOS, CCD and photodiodes were notoriously well known light receiving elements at the time of the invention.

Claim 13 lacks an inventive step under PCT Article 33(3) as being obvious over Kawashima. Kawashima suggests that the processor is within the operating end of the scope device and thus fails to disclose that the processor is external to the device. Locating the processor external to the device would have been an obvious design expedient since such shifting of the processor location to an external one would desirably make the device smaller and lighter, while affording the same processing capabilities. In addition, replacement of the processor if external would not require destroying the sealed nature of the scope.

Claim 13 lacks an inventive step under PCT Article 33(3) as being obvious over Avni et al. Avni et al. disclose the processor is within the operating end of the scope device and thus fails to disclose that the processor is external to the device. Locating the processor external to the device would have been an obvious design expedient since such shifting of the processor location to an external one would desirably make the device smaller and lighter, while affording the same processing capabilities. In addition, replacement of the processor if external would not require destroying the sealed nature of the capsule.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- 1 [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- 2 [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
- 3 [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4 [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.
It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)".

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.